

Date: 10. Aug. 2023

Urgent Field Safety Notice **Erytra Eflexis® analyzer**

Potential misinterpretation of results from a multiple techniques profile automatically cancelled and rescheduled due to an error situation

For Attention of: Distributors and Health Care Professionals, who are using Erytra Eflexis analyzer Software version 3.0.1.

Contact information

For additional information, please contact your local service representative at


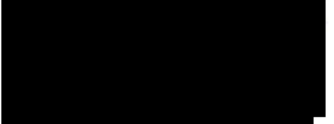
Country	Phone Contact	Email Contact
Austria	+49 69 660 593 380	service.dach@grifols.com
Brazil	+55 11 2131 7000	suporte.brasil@grifols.com
Chile	+56 999910887	soptecdiagnostic.chile@grifols.com
Czech Republic	+420 800 023 087	objednavky.sro@grifols.com
France	+33 4 42 544 405	sav-ih.gf@grifols.com
Germany	+49 800 82 53 286	service.dach@grifols.com
United Kingdom	+44 84 52 41 30 90	service.uk@grifols.com
Italy	+39 050 875 51 24	italiaassistenza@grifols.com
Poland	+48 22 378 85 68	service.Poland@grifols.com
Portugal	+351 933 021 148	service.portugal@grifols.com
Spain	+34 900 878 437	atencionclientes@grifols.com
Switzerland	+41 26 492 8702	service.ch@grifols.com

Urgent Field Safety Notice (FSN) **Erytra Eflexis® analyzer**

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1. Information on Affected Devices	
1	1. Device Type(s)
.	Automated Blood Typing System
1	2. Commercial name(s)
.	Erytra Eflexis
1	3. Unique Device Identifier(s) (UDI-DI)
.	08436583730942
1	4. Primary clinical purpose of device(s)
.	Erytra Eflexis is a fully-automated analyzer designed to automate in vitro immunohematological testing of human blood utilizing gel card technology, including Blood Grouping, Antigen Typing, Antibody Screening, Antibody Identification, Compatibility Tests and Direct Antiglobulin Tests.
1	5. Device Model/Catalogue/part number(s)
.	ref. 210600
1	6. Affected serial or lot number range
.	Software version 3.0.1

2 Reason for Field Safety Corrective Action (FSCA)	
2	1. Description of the product problem
.	Grifols received a complaint in which during processing a profile that includes multiple techniques, a card lost error arose. After this, the affected technique of the profile is cancelled and the instrument rescheduled it again. Afterwards, even the instrument has only the results from one of the techniques, the analyzer gave an interpretation that can be incorrect.
2	2. Hazard giving rise to the FSCA
.	The analyzer may give incorrect interpretations of a profile that includes multiple techniques under certain conditions.
2	3. Probability of problem arising
.	The issue can only occur in a profile with more than one technique and with common interpretation between those techniques. The issue occurs due to a mismanagement of different concurrent software tasks during an automatic reschedule of the technique driven after an error situation. If there is no common interpretation between techniques, the issue will lead to a partial result reported. The probability of occurrence is deemed to be very low as two software actions must happen at the same time.
2	4. Predicted risk to patient/users
.	An incorrect interpretation of the results by the analyzer can compromise patient safety if went undetected by the Laboratory Users.
2	5. Further information to help characterise the problem
.	The issue affects Erytra Eflexis Software version 3.0.1. The occurrence of this issue is improbable in previous software versions based on the investigation conducted at Grifols.

4. General Information	
4.	1. FSN Type New
4.	2. Further advice or information already expected in follow-up FSN? No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name Diagnostic Grifols S.A.
	b. Address Passeig Fluvial, 24, 08150, Parets Del Vallès, Spain
	c. Website address www.grifols.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.
4.	5. Name/Signature  Technical Director 

Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.</p> <p>Please transfer this notice to other organisations on which this action has an impact.</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.</p>